

Claim Rejection Under 35 USC §112

The Examiner has rejected claims 1-10 under 35 U.S.C. §112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. It is believed that this rejection has been rendered moot because of the amendment to claims 1 and 8 wherein the term "about" has been deleted.

Withdrawal of this rejection is respectfully solicited.

Claim Rejection Under 35 USC §102

The Examiner's rejection of claims 1, 2 and 5 under 35 USC §102(a) as being anticipated by the Atkins Ready-To-Drink shakes (Product Alert, November 13, 2000) (Reference V) is traversed. The article, including the title itself, says nothing more than the Atkins product line will be distributed exclusively by a New York based firm. It simply mentions that a ready-to-drink, high protein shake in vanilla, chocolate and strawberry flavors would be available. The shakes are "claimed to contain calcium and 22 other essentially nutrients, to have no added sugar and to be packaged in 11 ounce cans." This Reference V is absolutely devoid of any details which would allow one to apply this reference under 35 USC §102.

The Examiner goes on to say that the Applicants have referred to the Atkins product and "it appears that Applicants are using the Atkins formula to create the claimed product." As pointed out on page 2 of the application, one aspect of the present invention relates to the development of a good tasting and physically stable liquid or ready-to-drink (RTD) nutritional product that follows the Atkins diet. Challenges in producing such a RTD enteral formula include finding substitutes for simple sugars to make the product taste good, using a blend of proteins that do not cause processing viscosity or shelf-life stability issues at the high per serving levels desired, and a product that possesses soy protein and a specific mixture of vegetable oils that has good shelf life, physical stability, mouthfeel and taste. It is Applicants'

position that it is the unique combination of products as presently claimed that results in a RTD that is both pleasing to taste and physically stable over long periods of storage.

Most incredibly, the Examiner then goes on to recite that the nutrition fact list for Café au Lait shake was obtained from the Internet and "...provides the ingredients and amounts." Reference U has no dates, is not tied to the press release of Reference V, and further fails to disclose a ready-to-drink nutritional product that contains a fat component that comprises at least 3% of calories from omega-6 fats and at least 0.5% of calories from omega-3 fats. Further, the suggestive combination of References U and V fail to disclose a ready-to-drink nutritional product that comprises 53-62% by weight of calories from protein, wherein the protein is a mixture of soy protein isolate and calcium caseinate. Reference U fails to suggest any kind of omega-3 or omega-6 content and has no soy protein.

In light of the amendment to claim 1, the Examiner's rejection under 35 USC §102(a) has been overcome and should be withdrawn.

The Examiner's rejection of claims 1-3 and 5 under 35 USC §102(b) as being anticipated by Atkins Shake Mix (New York Times, January 11, 2000) (Reference X) in light of the Atkins Cappuccino Shake Mix label (Reference U) is traversed. Contrary to the Examiner's assertion, Reference X does not set forth a date when the Atkins mix was used. There is no product description in Reference X and it doesn't even mention the cappuccino product. The Reference U label discloses the ingredients, however, for the reasons that Reference W is insufficient, also apply to Reference U. More specifically, there is no mention of omega-3 fatty acids and omega-6 fatty acids in the product and no mention of soy protein.

Applicants strenuously object to the Examiner's improper attempt to combine these two references in an improper manner. With no information tying Reference X to Reference U, the Examiner has engaged in an improper combination of prior art. In light of the amendment to the claims wherein at least 3% of the calories of the fat component or omega-6 fats, and at least 5% of calories are omega-3 fats, precludes References X and U from anticipating claim 1 presently

before the Examiner. Further, the requirement of claim 1 wherein 53-62% of the calories are from protein and wherein said protein is a mixture of soy protein isolates and calcium caseinate, is totally missing from the references. For these reasons, it is believed that the Examiner's rejection of claims 1-3 and 5 under 35 USC §102(b) has been overcome. Withdrawal of that rejection is respectfully solicited.

**Claim Rejections Under 35 USC §103**

The Examiner's rejection of claims 4 and 6-10 under 35 USC §103(a) as being unpatentable over Atkins Ready-to-Drink shakes is traversed. The Examiner is apparently unable to find references with the required specificity to render obvious or anticipate claims 4 and 6-10. Essentially, claim 10 is the product that was prepared as described in the Example of the present application. As pointed out in the specification, the inventors desire to prepare a high protein/low carbohydrate, ready-to-drink beverage that has good taste and proper viscosity to allow the consumer to drink an entire container. The present inventors, through experimentation, have arrived at a mixture of components that establishes a cooperative relationship between those components to produce a new and unexpectedly functional ready-to-drink, high protein/low carbohydrate beverage.

As pointed out on page 2 of the application, the inventors have discovered a good tasting and physically stable liquid or RTD nutritional product that overcomes the challenges in producing a high fat, high protein beverage. The challenges overcome in producing the inventive enteral formula involve finding substitutes for simple sugars to make the product taste good and a blend of proteins that do not cause processing viscosity or shelf-life stability issues while at the same time also providing 50% of the daily recommended intake of soy in one 11 ounce serving. On top of overcoming that hurdle, was the benefits realized in using a combination of corn oil, high oleic sunflower oil, and canola oil to arrive at an oil blend that

provides at least 3% of calories from omega-6 fats and at least 0.5% of calories from omega-3 fats.

While attempting to mimic the Atkins diet in terms of percent calories from fat, protein and carbohydrates, the inventive nutritional beverage utilizes a specific mixture of vegetable oils and soy protein isolates in combination with calcium caseinate to achieve a nutritional supplement with good shelf-life, physical stability, mouthfeel and taste. The Examiner's improper combination of the references under 35 USC §103 cannot be repaired by resorting *In re: Levin.*

As pointed out above, the present application does establish a cooperative relationship between the selected ingredients to product a new and useful, enteral nutritional product. The Examiner's inability to find any one reference or combination of references that would anticipate or render obvious claim 1, as presently amended, is testimony to the inventive nature of this nutritional product.

### Conclusion

It is respectfully submitted that each and every objection raised by the Examiner has been overcome. Applicants earnestly solicit a Notice of Allowance relative to the claims presently before the Examiner. Should the Examiner have any questions prior to passing this case onto allowance, he is invited to contact the undersigned attorney.

Respectfully submitted,

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in re:

Amendment dated 12/10/02

MARKED UP VERSION SHOULD NOT CHANGES

We claim:

1. A ready-to-drink nutritional product comprising:
  - a) from about 37 to 47% of calories from fat;  
*ADD: wherein said fat comprises at least 3% of calories from Omega-6 fats and at least 0.5% of calories from Omega-3 fat*
  - b) from about 53 to 62% of calories from protein;  
*ADD: wherein said protein is a mixture of soy protein isolate and calcium caseinate*
  - c) less than 5% of calories from carbohydrates;
  - d) vitamins;
  - e) minerals; and
  - f) water.
2. The ready-to-drink nutritional product according to claim 1 wherein said fat comprises vegetable oil.
3. The ready-to-drink nutritional product according to claim 1 wherein said fat consists of corn oil, safflower or sunflower oil, canola oil and mixtures thereof.
4. The ready-to-drink nutritional product according to claim 1 wherein said fat is a mixture of corn oil, high oleic safflower or sunflower oil and canola oil.
5. The ready-to-drink nutritional product according to claim 1 wherein said protein is selected from the group consisting of soy protein, caseinates, milk protein isolates and mixtures thereof.  
*(cancel)*
6. The ready-to-drink nutritional product according to claim 1 wherein said protein is a mixture of soy protein isolate and calcium caseinate.  
*(cancel)*
7. The ready-to-drink nutritional product according to claim 1 additionally comprising potassium citrate and DMP.
8. A ready-to-drink nutritional product comprising by weight:
  - a) about 0.4 to about 0.6% corn oil;

- b) about 0.5 to about 0.8% high oleic sunflower oil;
- c) about 0.8 to about 1.1% canola oil;
- d) about 0.1 to about 0.2% lecithin;
- e) about 4.0 to about 6.0% soy protein isolate;
- f) about 4.0 to about 6.0% calcium caseinate; and
- g) about 83 to about 93% water.

9. The ready-to-drink nutritional product according to claim 8 additionally comprising potassium citrate and DMP.

10. The ready-to-drink nutritional product according to claim 8 additional comprising vitamins and minerals.

Replacement  
pages submitted with  
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We claim:

1. A ready-to-drink nutritional product comprising:
  - a) from 37 to 47% of calories from fat wherein said fat comprises at least 3% of calories from omega-6 fats and at least 0.5% of calories from omega-3 fats;
  - b) from 53 to 62% of calories from protein wherein said protein is a mixture of soy protein isolate and calcium caseinate;
  - c) less than 5% of calories from carbohydrates;
  - d) vitamins;
  - e) minerals; and
  - f) water.
2. The ready-to-drink nutritional product according to claim 1 wherein said fat comprises vegetable oil.
3. The ready-to-drink nutritional product according to claim 1 wherein said fat consists of corn oil, safflower or sunflower oil, canola oil and mixtures thereof.
4. The ready-to-drink nutritional product according to claim 1 wherein said fat is a mixture of corn oil, high oleic safflower or sunflower oil and canola oil.
5. *Cancelled by amendment*
6. *Cancelled by amendment*
7. The ready-to-drink nutritional product according to claim 1 additionally comprising potassium citrate and DMP.
8. A ready-to-drink nutritional product comprising by weight:
  - a) 0.4 to 0.6% corn oil;
  - b) 0.5 to 0.8% high oleic sunflower oil;
  - c) 0.8 to 1.1% canola oil;

- d) 0.1 to 0.2% lecithin;
- e) 4.0 to 6.0% soy protein isolate;
- f) 4.0 to 6.0% calcium caseinate; and
- g) 83 to 93% water.

9. The ready-to-drink nutritional product according to claim 8 additionally comprising potassium citrate and DMP.

10. The ready-to-drink nutritional product according to claim 8 additional comprising vitamins and minerals.